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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,348	01/19/2001	Dewen Qiu	19603/2986 (CRF D-1940B)	7683

7590 05/01/2003

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EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,348	QIU ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-77* is/are pending in the application.

4a) Of the above claim(s) *45-48,54-57,65-68 and 74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-44,49-53,58-64,69-73 and 75-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 41-54 and 58-77, to the extent they read on a nucleic acid 3encoding a hypersensitive response elicitor protein of *Erwinia amylovora*) in Paper No. 10 is acknowledged.

The traversal is on the grounds that Groups I and II are sufficiently related that there would be common areas of search and consideration (response pg 1). This is not found persuasive because the different methods have different starting materials, different method steps and different end products; thus, the different methods are independent and distinct. The different methods have different considerations and would require different searches, because a search on a method of topically applying a protein would not find art on transformation with a nucleic acid.

The traversal is also on the grounds that the restriction among the various nucleotide sequences that encode different hypersensitive response elicitor proteins is improper because it ignores the relatedness of the proteins they encode. The response reiterates the Declaration of Dr. Zhong-Min Wei, filed with the response, and both will be summarized together (all cited references were sent with the Declaration): Hypersensitive response elicitor proteins are an art-recognized class of proteins and share the unique ability to cause distinct plant responses. Gopalan et al (1996, Plant Dis. 80:604-610) teaches that the hypersensitive response results from an incompatible interaction between plant pathogens and non-host plants and this reaction is distinct from a compatible interaction. Gopalan also teaches that hypersensitive response elicitor proteins from one genus are often homologous to elicitors of a different species and genus.

Bauer et al (1995, MPMI 8:484-491), Cui et al (1996, MPMI 9:565-573), Ahmad et al (1996, 8th Int'l Cong. Molec. Plant Microbe Inter.), and Preston et al (1995, MPMI 8:717-732) teach that a nucleic acid encoding a hypersensitive response elicitor protein from one bacterial species was used to isolate a nucleic acid encoding a hypersensitive response elicitor protein from the same genus. Bonas (1994, Current Topics in Microbiol. Immunol. 192:79-98), Alfano et al (1997, J. Bacteriol. 179:5655-5662), and Swanson et al (1999, Phytopath. 90:S75) teach that genes encoding hypersensitive response elicitors are arranged in gene clusters. Bogdanove et al (1996, Molec. Microbiol. 20:681-683) teach that most hypersensitive response elicitors are secreted through the type III secretion system. Bonas (*op cit*) and Wei et al (2000, MPMI 13:1251-1262) teach that the genes are regulated by environmental factors. Bonas (*op cit*), Bonas (1994, Trends Microbiol. 2:1-2), Alfano (*op cit*), Gopalan (*op cit*), and Fan et al (WO 01/98501) teach that hypersensitive response elicitor proteins share common characteristics and structure. Wei et al al (1996, Acta Hort. 411:223-225) Alfano (*op cit*), Strobel et al (1996, Plant J. 9:431-439) and Qui et al (US Patent 6,277,814) teach that hypersensitive response elicitors induce plant responses that include disease resistance to a broad range of pathogens and enhance plant growth. The Declaration presents data showing that topical application of the hypersensitive response elicitor protein from *Xanthomonas campestris* pv. *pelargonii* (HreX) induced resistance to diseases caused by other pathogens and enhanced plant growth; topical application of the hypersensitive response elicitor protein from *Pseudomonas syringae* also enhanced plant growth. Wei et al (WO 00/28055) teach that HrpN induces resistance to plant stress, and the Declaration presents data showing that topical application of HreX also induces plant stress resistance.

This is not found persuasive because, as stated in MPEP 803.04, nucleotide sequences encoding different proteins are structurally distinct chemical compounds, are unrelated to each other, and constitute independent and distinct inventions. Thus, methods utilizing different nucleic acid sequences are also independent and distinct inventions. Additionally, each nucleic acid would require a separate search.

It is noted that Applicant does not state that prior art regarding use of a nucleic acid encoding one hypersensitive response elicitor would render the others obvious.

The traversal is also on the grounds that claims 41, 58, 61 and 75 are linking claims, but were not so treated in the restriction requirement, and that certain other claims are sub generic by source organism (response pg 7). Examiner responds that the linking claims will be treated as linking claims.

The traversal is also on the grounds that SEQ ID NOs:2, 4, 6 and 8 are patented or known in the art, and Applicant is merely claiming their use. Applicant urges that limiting the claimed invention to use of a nucleic acid encoding a specific hypersensitive response elicitor negates the breath of the invention as claimed (response pg 7). This is not found persuasive because the linking claims will be so treated; thus, the breadth of the invention is not negated.

Lastly, Applicant urges that not one of the pending claims is drawn to a single nucleotide sequence and thus restriction to a single disclosed nucleotide sequence is improper. Examiner responds that the claims will be examined to the extent they read on a nucleic acid encoding hypersensitive response elicitor proteins from the elected bacterial species, *Erwinia amylovora*.

The requirement, with the exception of the linking claims, is still deemed proper and is therefore made FINAL.

A search of the prior art also found art on a method of imparting pathogen resistance to plants by transformation with a nucleic acid encoding a hypersensitive response elicitor from *Erwinia chrysanthemi*. As a courtesy to Applicant, that invention will also be examined.

Claims 45-48, 54-57, 65-68 and 74 are drawn to non-elected inventions/hypersensitive response elicitors, and are thus withdrawn from consideration. Claims 41-44, 49-53, 58-64, 69-73 and 75-77 are examined to the extent they read on a nucleic acid encoding a hypersensitive response elicitor protein from *E. amylovora* or *E. chrysanthemi*.

2. Certain references in the information disclosure statement filed with the application fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the citation was incomplete or a translation was missing; those citations have been crossed out. Those references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

3. Claims 41-44, 49-53, 62-64, 69-73 and 75 are objected to because of the following informalities:

Claims 41-44, 49-53, 62-64 and 69-73 start with an improper article.

There is an improper article before "process" in claim 75, line 1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 41-44, 49-53, 58-64, 69-73 and 75-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to use of a multitude of DNA molecules that encode hypersensitive response elicitor proteins from *E. amylovora* or *E. chrysanthemi*. In contrast, the specification only describes one such coding sequence from *E. amylovora* (SEQ ID NO:4) and one from *E. chrysanthemi* (SEQ ID NO:2). Applicant does not describe other DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

For example Applicant does not describe the nucleic acids encoding the DspE, DspF, and HrpW hypersensitive response elicitor proteins from *E. amylovora* (Bogdanove et al, WO 99/07206, and Kim et al, WO 99/07208).

Because the sequences are not described, the method of using the sequences to impart pathogen resistance to plants is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 41-44, 49-53, 58-64, 69-73 and 75-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

It is unclear in claims 41 and 61 if everything following "comprising" is intended to modify "plants" or "method". By position in the claim it modifies "plants". If Applicant intended it to modify "method", it is suggested that "comprising" be replaced with --, wherein the method comprises--.

Claim 41 is indefinite in its recitation of "conditions effective to impart pathogen resistance" in line 9, and claims 61 and 75 are indefinite in its recitation in lines 3-4. What these conditions are is unclear, given that the phrase is not defined by the specification or the claims.

It is unclear in claims 42-44 and 62-64 what it means for polypeptide or protein to "correspond" to "that derived from" a bacterial species. Does it mean the nucleic acid encoding the polypeptide or protein was isolated from the bacterial species? Does it mean the nucleic acid encoding the polypeptide or protein was modified in some manner, and if so, how was the sequence of the polypeptide or protein affected?

Claim 53 lacks antecedent basis for the limitation "the propagated plants" in line 4.

It is unclear in claims 59 and 76 if the seeds comprise the nucleic acid encoding the hypersensitive response elicitor.

Claim 61 lacks antecedent basis for the limitation "the transgenic plant". Amendment to address this rejection would also affect dependent claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 41-43, 49-53, 58-63, 69-73 and 75-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al (US Patent 5,850,015, filed June 1995).

As the phrase "conditions effective to impart pathogen resistance" is not defined by the specification or the claims, for purposes of examination, propagation or transformation under any conditions was assumed to be effective to impart pathogen resistance.

Bauer et al teach plants, including those in instant claims 50-51, transformed with a nucleic acid encoding a hypersensitive response elicitor from *E. chrysanthemi* (claims 9-12) and a method of imparting pathogen resistance to plants by transformation with the nucleic acid (claims 13-19). Seeds would be produced and propagated in the production of those transgenic plants. Bauer et al also teach topical application of the hypersensitive response elicitor protein to the transformed plants (column 14, lines 33-42).

10. Claims 41-42, 44, 52, 58-62, 64, 72 and 75-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Beer et al (US Patent 6,174,717, filed July 1992).

The applied reference has a common [assignee OR inventor] with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As the phrase "conditions effective to impart pathogen resistance" is not defined by the specification or the claims, for purposes of examination, propagation or transformation under any conditions was assumed to be effective to impart pathogen resistance.

Beer et al teach plants transformed with a nucleic acid encoding a hypersensitive response elicitor from *E. amylovora* (claim 16). The method of producing the plants would be identical to the methods of imparting pathogen resistance to plants, as transformation of the plants would be required and because seeds would be produced and propagated in the production of those transgenic plants.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 41-44, 49-53, 58-64, 69-73 and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer et al (US Patent 5,850,015, filed June 1995) in view of Wei et al (1992, Science 257:85-88).

The claims are drawn to method of imparting pathogen resistance to plants by planting a seed transformed with a nucleic acid encoding a hypersensitive response elicitor from *E. amylovora* and propagating a plant from the seed or by transformation of a plant with the nucleic acid.

The teachings of Bauer et al are discussed above. Bauer et al do not disclose a nucleic acid encoding a hypersensitive response elicitor from *E. amylovora*.

Wei et al teach a nucleic acid encoding a hypersensitive response elicitor from *E. amylovora* (Figure 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of imparting pathogen resistance to plants as taught by Bauer et al, to substitute the nucleic acid encoding a hypersensitive response elicitor from *E. amylovora* described in Wei et al. One of ordinary skill in the art would have been motivated to do so because Bauer et al teach that the *E. chrysanthemi* protein has many similarities to the *E. amylovora* protein, including physical properties, and elicitation of the same plant response (column 23, lines 31-53). Thus, substitution of one nucleic acid encoding a hypersensitive response elicitor for another is an obvious design choice.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 41-42, 44, 52, 58-62, 64, 72 and 75-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 5,850,015. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding a specific hypersensitive response elicitor from *E. amylovora*, as claimed in the issued patent, would be a species of the genus of plants transformed with a nucleic acid encoding any hypersensitive response elicitor from *E. amylovora* or any source, as claimed in the instant application. Furthermore, the method of producing the plants claimed in the issued patent would be identical to the methods of

imparting pathogen resistance to plants, as claimed in the instant application, as transformation of the plants would be required and because seeds would be produced and propagated in the production of those transgenic plants.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
April 25, 2003

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